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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/606,569 06/29/00 BIGAZZI

M 67206

023872
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SCARBOROUGH STATION
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HM22/1101

EXAMINER

DEBERRY, R

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

11/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/606,569

Applicant(s)

BIGAZZI, MARIO

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 31 August 2001 (Paper No. 7) has been entered in full. The information disclosure statement filed 31 August 2001 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of the specification as set forth at pages 2-3 of the previous Office Action (04 April 2001 Paper No. 5) is *withdrawn* in view of the amendment (31 August 2001 Paper No. 7).

The rejection of claims 1-5 under 35 USC 112, first paragraph, scope of enablement as set forth at pages 5-7 of the previous Office Action (04 April 2001 Paper No. 5) is *withdrawn* in view of the amendment (31 August 2001 Paper No. 7).

The rejection of claims 1-5 under 35 USC 112, first paragraph, written description as set forth at pages 7-8 of the previous Office Action (04 April 2001 Paper No. 5) is *withdrawn* in view of the amendment (31 August 2001 Paper No. 7).

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §

1.821 through 1.825 because no submission of a computer readable form (CRF) and paper copy sequence has been submitted. Applicant must provide a CRF and a paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification. Applicant must also submit a statement that the content of the paper and computer readable copies are the same and include no new matter. Applicants is given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 1-5 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is in reference to the terms "Th2-dominated disease" and "pathogenic Th2 response". The basis for this rejection was set forth at page 9 of the previous Office Action (04 April 2001 Paper No. 5).

Applicant's arguments (page 9, 31 August 2001 Paper No. 7) have been fully considered but are not deemed persuasive for the following reasons.

The reference discussed in the double patenting rejection provides evidence that the diseases cited in the patent are Th2-dominated diseases, which would cause a pathogenic Th2 response. The reference however, does not provide evidence of what diseases are encompass by the term Th2-dominated diseases and pathogenic Th2 response, therefore the metes and bounds cannot be determined.

Double Patenting

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-28 of U.S. Patent No. 5,952,296 (cited in IDS, Paper No. 2) in view of Piccinni et al. The basis for this rejection was set forth at pages 3-5 of the previous Office Action (04 April 2001 Paper No. 5).

Applicant's arguments (pages 10-16, 31 August 2001 Paper No. 7) have been fully considered but are not deemed persuasive for the following reasons.

Applicant states that the content of Eur. J. Immunol. 1999 29:2241-2247(Piccinni-2241) is essentially identical to that of the instant Bigazzi application in regard to the crux of the present invention. Applicant points out that Piccinni-2241 was published less than 1 year before the filing date of the instant application and that the co-authors of Piccinni-2241 merely assisted Bigazzi in his work but were not co-inventors with him as regards the present invention and thus Piccinni-2241 is not a valid reference herein under 35 USC 102 (b). Applicant states that Annals of the New York Academy of Sciences: Neuroimmuno modulation 2000, 917:844-852, "Environmental Factors Favoring the Allergen-specific Th2 response in Allergy Subjects (Piccinni-844) is only relevant to the extent of the statements on the lower half of page 847. Applicant states that footnote 35 as shown on page 851 of Piccinni-844, cites Piccinni-2241. Applicant states that Piccinni-2241 is the best evidence that the concept of the instant invention existed prior to the Piccinni-844 thus Piccinni-844 like Piccinni-2241 is not a valid reference under 35 USC 102 (b) or under 35 USC 102 (a). Applicant states that it is not believed that Applicant Mario Bigazzi need to furnish a declaration per CFR 1.131 (Rule

131). Applicant states that since Piccinni-844 is clearly not a valid reference herein, the double patenting rejection on the combination of Bigazzi-296 and Piccinni-844 cannot stand. Hence, there is no need to file a terminal disclaimer herein. In addition, Applicant states that absent pre-knowledge of the present invention; there would be no reason for the artisan aware of Bigazzi-296 to administer relaxin (RLX) or a derivative thereof to treat a condition as contemplated by the instant claims. Applicant states that the art would not have the benefit of the present invention treatment method concept even if such method of use were inherently affected upon the Bigazzi-296 administering of RLX or a derivative thereof for the Bigazzi-296 taught treatment purposes. Applicant states that merely because Bigazzi-296 shows that RLX or a derivative thereof is usable to treat said conditions (1) to (6) deriving from histamine release, would tell the artisan nothing about the instant methods of use of RLX or derivatives thereof.

Contrary to Applicants assertion, the second reference was used as evidence to show that the patented method was in fact a Th2-dominated disease inherently; therefore whether or not the second reference qualifies as prior art under 102 is irrelevant since even post filing date art can be used as evidence of inherency. The claims in the instant application are broadly drawn to treating Th2-dominated diseases and inhibiting pathogenic Th2 responses. The references of both Piccinni-2241 and Piccinni-844 show that the diseases cited in Bigazzi-296 are Th2-dominated diseases and that Th2 is involved in the release of histamines (a pathogenic Th2 response). The references also teach that Th1 cells produce IFN- γ and both IFN- γ and RLX play a

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negative regulatory role in the development of Th2 cells. Furthermore, Applicant has admitted that the content of Eur. J. Immunol. 1999 29:2241-2247(Piccinni-2241) is essentially identical to that of the instant Bigazzi application in regard to the crux of the present invention. The species claims in Bigazzi-296 render the genus claims in the instant application obvious.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

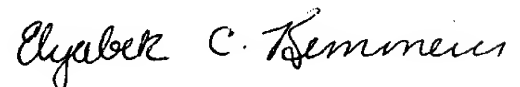
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
October 23, 2001



ELIZABETH KEMONEIS
PRIMARY EXAMINER